

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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#11  
DB  
8/21/02

In re Patent Application of

WOOD et al.

Serial No. 09/701,747

Filed: January 29, 2001

For: ION CHANNELS

Atty. Ref.: 620-123

Group: 1646

Examiner: Basi

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August 16, 2002

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

RESPONSE

Responsive to the Official Action dated July 16, 2002, the applicants elect, with traverse, the subject matter of the Examiner's Group I for further prosecution in the above. Reconsideration and withdrawal of the restriction requirement are requested in view of the following comments.

The Examiner is urged to appreciate that Rule 13.2 PCT (1st sentence) states:

*'Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features'.*

For the assessment of unity under Rule 13 PCT, it does not matter whether or not certain 'inventions' are obvious or 'distinct' over other 'inventions'. Nor does not matter whether the claimed process steps are materially different or whether the claimed

products are materially, structurally or functionally different, as is apparently the basis for the Examiner asserting a lack of unity of invention. See, page 3 of the Office Action dated July 6, 2002 (Paper No. 9). Claimed products or processes may differ in any way at all as long as they possess a relationship which involves a special technical feature.

The only criterion to be assessed in determining unity of invention under Rule 13 PCT is whether groups of claims or 'inventions' have a relationship which involves either the same or a corresponding special technical feature. It is irrelevant whether or not the claimed products or processes differ materially.

Note also that possession of a technical relationship which involves the same or a corresponding special technical feature is not necessarily the same as a specific recital of the same or a corresponding special technical feature.

For the reasons set out below, all the present claims possess unity of invention as defined in Rule 13 PCT.

The present invention relates to the characterisation of an  $H^+$  gated cation channel from a sensory neuron cDNA library.

Claims 1-19, 21-27, and 38-41, which relate to the nucleic acid and protein sequences, in Group I. The special technical feature shared by these sequences is considered by the Examiner to be the protein of SEQ ID NO:2 encoded by the nucleic acid of SEQ ID NO: 1.

Group II (claims 20 and 42) relates to methods of producing derivatives by modifying the nucleic acid sequence of SEQ ID NO:1.

Rule 13.2 PCT (2nd sentence) provides a definition of a 'special technical feature':

*'The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art'*

The feature of claims 20 and 42 which defines a contribution over the art is the sequence which is being modified, which is the sequence of SEQ ID NO:1. The relationship between the claims of group I and claims 20 and 42 therefore involves the same special technical feature and there is unity between Group II and Group I.

Group III (claims 28-30 and 43) relates to methods of influencing the electrophysiological and/or pharmacological properties of a cell by altering expression of a nucleic acid which encodes a protein of SEQ ID NO:2.

The feature of claims 28-30 and 43 which defines a contribution over the art is that the nucleic acid whose expression is altered encodes SEQ ID NO:2. The other features of these claims are known in the art (i.e. expression of genes encoding ion channels is known to alter the properties of a cell) and do not define a contribution over it. The special technical feature of claims 28-30 and 43 is therefore protein of SEQ ID NO:2, which may, for example be encoded by the nucleic acid of SEQ ID NO: 1. The relationship between the claims of group I and claims 28-30 and 43 therefore involves the same special technical feature and there is unity between Group III and Group I.

Group IV (claim 31) relates to methods of influencing the electrophysiological and/or pharmacological properties of a cell by altering expression of a nucleic acid which is the complement of SEQ ID NO:1.

As the other features of claim 31 are known in the art (i.e. it is known per se to use anti-sense nucleic acid to influence the expression of genes encoding ion channels) and do not therefore define a contribution over it, the feature of claim 31 which defines the contribution over the art is that the expressed nucleic acid is the complement of SEQ ID NO:1.

The special technical feature of claim 31 is therefore the complementary sequence to SEQ ID NO: 1. SEQ ID NO: 1 and its complementary sequence are corresponding technical features within the meaning of Rule 13.1 PCT and the relationship between the claims of group I and claim 31 therefore involves a corresponding special technical feature. Thus, there is unity between Group IV and Group I.

Group V (claim 32) relates to transgenic animals which comprise a cell containing a heterologous nucleic acid encoding a protein of SEQ ID NO: 2.

As transgenic animals per se are known in the art, the feature of claim 32 which defines the contribution over the art is that the nucleic acid which encodes the protein of SEQ ID NO:2.

The special technical feature of claim 32 is therefore the nucleic acid which encodes the protein of SEQ ID NO:2 (e.g. SEQ ID NO: 1). The relationship between the claims of group I and claim 32 therefore involves the same special technical feature and there is unity between Group V and Group I.

Group VI (claims 33-36) relates to methods of identifying a substance having an ion-channel modulating activity using the protein of SEQ ID NO:2.

Methods of identifying substances having an ion-channel modulating activity are known in the art. The feature of claims 33-36 which defines a contribution over the art is the protein of SEQ ID NO:2.

The special technical feature of claims 33-36 is therefore the protein of SEQ ID NO:2. The relationship between the claims of group I and claims 33-36 therefore involves the same special technical feature and there is unity between Group VI and Group I.

Group VII (claim 37) relates to polypeptides which possess an antibody antigen binding site which specifically binds the protein of SEQ ID NO:2.

Polypeptides which possess an antibody antigen binding site are known per se in the art. The feature of claim 37 which defines a contribution over the art is that the binding site binds the protein of SEQ ID NO:2.

The special technical feature of claim 37 is therefore the protein of SEQ ID NO:2. The relationship between the claims of group I and claim 37 therefore involves the same special technical feature and there is unity between Group VII and Group I.

Group VIII (claim 44) relates to methods of identifying a substance having an ion-channel modulating activity using a cell which contains a heterologous nucleic acid encoding the protein of SEQ ID NO:2.

Methods of identifying substances having an ion-channel modulating activity employing cells which express heterologous nucleic acids are per se known in the art.

The feature of claim 44 which defines a contribution over the art is that the methods employ nucleic acid which encodes the protein of SEQ ID NO:2.

The special technical feature of claim 44 is therefore the protein of SEQ ID NO:2. The relationship between the claims of group I and claim 44 therefore involves the same special technical feature and there is unity between Group VIII and Group I.

It is further noted that the claims of Group VIII actually fall within the scope of the claims of Group VI and define a subset of methods which employ protein which has been expressed in cells from heterologous nucleic acid. Group VIII thus includes all the features of Group VI along with additional features.

Group IX (claim 45) relates to methods of identifying a substance having an ion-channel modulating activity using a transgenic organism which contains a cell containing a heterologous nucleic acid encoding the protein of SEQ ID NO:2.

Methods of identifying substances having an ion-channel modulating activity employing transgenic animals which contain cells which express heterologous nucleic acids are known in the art. The feature of claim 45 which defines a contribution over the art is that the nucleic acid which is expressed encodes the protein of SEQ ID NO:2.

The special technical feature of claim 45 is therefore the protein of SEQ ID NO:2. The relationship between the claims of group I and claim 44 therefore involves the same special technical feature and there is unity between Group VIII and Group I.

It is further noted that the claims of Group IX actually fall within the scope of the claims of both Group VIII and Group VI and, in fact define a subset of methods within these groups wherein protein is employed which has been expressed in cells from

heterologous nucleic acid within a transgenic animal. Group IX thus includes all the features of Group VI and Group VIII along with additional features. Given this relationship, there is clearly unity of invention between these groups of claims.

Group IX also shares a special technical feature with Group V i.e. a transgenic organism which contains a cell containing a heterologous nucleic acid encoding the protein of SEQ ID NO:2. Given this relationship, there is clearly unity of invention between these groups of claims.

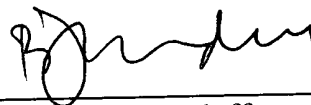
For the reasons described above, the restriction requirement should be withdrawn.

Moreover, the Examiner's restriction requirement has not been fully explained beyond the assertion that the claims do not relate to a single general inventive concept because they lack the same or corresponding technical feature. Specifically, the Examiner merely recites the subject matter of the indicated Groups on page 3 without identifying any distinguishing aspect of any separate technical features of the claimed invention. Withdrawal of the restriction requirement and an action on the merits of the claimed subject matter are requested.

Respectfully submitted,

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